



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93525d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 300374607

September 27, 2002

Naoichiro Niwano, President
San Jose Fish, Inc.
1201 Martin Avenue
Santa Clara, CA 95050

WARNING LETTER

Dear Mr. Niwano:

On July 31 and August 1, 2002, the U.S. Food and Drug Administration (FDA) inspected your seafood processing facility, located at 1201 Martin Avenue, Santa Clara, California. We found that you have serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your tuna to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov. See attached handout, which gives information on how to obtain the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. This guidance is also available electronically through links in FDA's home page.

Your serious HACCP deviations are as follows:

You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). However, your firm does not have a HACCP plan for fresh, refrigerated tuna to control the food safety hazard of histamine formation. A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption."

We acknowledge your letter dated August 13, 2002 in which you state that (1) you have enrolled in a HACCP training course, and (2) you have implemented a checklist for the individual who picks up fresh seafood from your vendors. Although we approve of your

enrolling in the HACCP training course, your letter does not adequately address the above deviations.

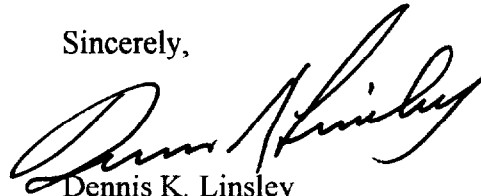
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Dennis K. Linsley
District Director
San Francisco District

Enclosure:

- Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001